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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,647	04/18/2001	William Ernest Alborn, JR.	X-13168	9595

7590                    05/06/2003

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[REDACTED] EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
1623	12

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/833,647	ALBORN, ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 February 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 11 is/are allowed.
- 6) Claim(s) 2-10 and 12-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                             | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10-11</u> . | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Objections/Rejections Set For the in Office Action dated September 27, 2002***

1. Claims 13-24 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: all of the steps necessary to isolate Lipid II.
2. Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Leigh U.S. Patent 5,141,674 (Leigh).

***Applicant's Response dated February 20, 2003***

3. In the Response filed February 20, 2003, the specification was amended and claim 1 was canceled. Applicant presented arguments directed to the rejection of claims 13-24 under 35 U.S.C. 112, second paragraph. Claims 2-27 are pending. An action on the merits of claims 2-27 is contained herein below.
4. The rejection of claims 13-24 under 35 U.S.C. § 112, second paragraph, is maintained for the reasons of record set forth in the Office Action dated September 27, 2002.

***Response to Arguments***

5. Applicant's arguments filed February 20, 2003 have been fully considered but they are not persuasive.

Applicant argues that the only essential step for claims 13-24 is isolating the Lipid II at a pH greater than 6. Applicant's argument is not persuasive. Claims 13-24 are drawn to a "process for isolating" Lipid II wherein the process comprises "isolating said Lipid II". The only limitation set forth is that the isolation occur at a pH greater than 6. The claims do not set forth the material/composition from which Lipid II will be isolated, how said material/composition will be manipulated, nor does it set forth a final step in which the Lipid II is in hand in an isolated form. The active steps involved in the actual isolation of Lipid II are seen to be of critical importance. In the absence of positive, active steps, said claims are indefinite as one of ordinary skill in the art would not be apprised of the metes and bounds of the instantly claimed method.

***Allowable Subject Matter***

6. The indicated allowability of claims 2-10, 12, and 25-27 is withdrawn in view of the new grounds of rejection. The newly cited rejections follow herein.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 and 27 recite the variable "P"; however, "P" is also the symbol for the atom phosphorous. This ambiguity in regards to "P" renders the claims indefinite, as one of ordinary skill in the art would not be apprised as to whether "P" is phosphorous or is intended as a variable.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 12 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Heijenoort et al. *J. Bacteriol.* 1992, Vol. 174, pages 3549-3557 (Heijenoort). (Of record).

Heijenoort discloses isolated Lipid II (page 3549). Heijenoort discloses that Lipid II has been purified from a cell-free system in which it was allowed to accumulate to a certain extent by incubation of membranes with UDP-GlcNAc and radiolabelled UDP-MurNAc-pentapeptide (page 3550, column 2). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product

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was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 2-10, 12, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heijenoort et al. *J. Bacteriol.* **1992**, Vol. 174, pages 3549-3557 (Heijenoort). (Of record).

Claims 2-10, 12, and 26 are drawn to an isolated Lipid II compound. Claim 2 is drawn to a Lipid II compound of at least 50%. Claim 3 is drawn to a Lipid II compound of at least 60%. Claim 4 is drawn to a Lipid II compound of at least 70%. Claim 5 is drawn to a Lipid II compound of at least 80%. Claim 6 is drawn to a Lipid II compound of at least 90%. Claim 7 is drawn to a Lipid II compound of at least 95%. Claim 8 is drawn to a Lipid II compound of at least 98%. Claim 9 is drawn to a Lipid II compound of at least 99%. Claim 10 is drawn to a Lipid II compound of at least 99.5%. Claims 12 and 26 are drawn to a product-by-process (Lipid II). Claims 12 and 26 are rejected for the reasons set forth above under **102(b) Rejections** above, as anticipation is the epidemic of obviousness.

Heijenoort teaches isolated Lipid II (page 3549). Heijenoort teaches that Lipid II has been purified from a cell-free system in which it was allowed to accumulate to a certain extent by incubation of membranes with UDP-GlcNAc and radiolabelled UDP-MurNAc-pentapeptide (page 3550, column 2).

Heijenoort differs from the instantly claimed invention in that Heijenoort is silent on the extent of the purity of the Lipid II. Although Heijenoort does not explicitly teach that Lipid II is 99.5% pure, changing the form, purity or other characteristics of an old product does not render the novel form patentable where the difference in form, purity or characteristic was rendered obvious by the prior art. When claiming a purer form of a

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known compound, it must be demonstrated that the purified material possess properties and utilities not possessed by the unpurified material. *Ex parte Reed*, 135 USPQ 34, 36 (POBA 1961), *on reconsideration*, *Ex parte Reed*, 135 USPQ 105 (POBA 1961). Since no new properties and/or utilities have been set forth, the instantly claimed Lipid II is indeed *prima facie* obvious.

### ***Conclusion***

15. Claims 2-27 are pending. Claims 2-10 and 12-27 are rejected. Claim 11 appears to be free of the prior art. There are no teachings or suggestions in the prior art for the chemical synthesis of the Lipid II compound wherein the starting material is a protected disaccharide of Formula 14.

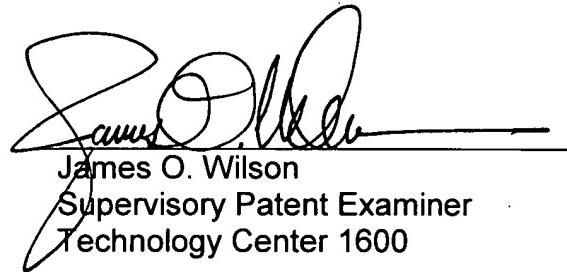
***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

ptl  
May 5, 2003